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10/526,830

02/06/2006

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EXAMINER

PURDY, KYLE A

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

10/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/526,830 | <b>Applicant(s)</b><br>KELLY ET AL. |  |
|                              | <b>Examiner</b><br>Kyle Purdy        | <b>Art Unit</b><br>1611             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02/20/2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 9-24 is/are pending in the application.
- 4a) Of the above claim(s) 10-19 and 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9, 20 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application***

1. The Examiner acknowledges receipt of the amendments filed on 08/13/2008 wherein claims 1-5 and 9-24 have been amended and claims 6-8 have been cancelled. Claim 24 is newly added..

2. Claims 1-5, 9, 20 and 24 are presented for examination on the merits. The following rejections and objections are made.

### ***Response to Applicants' Arguments***

3. Applicants arguments filed 08/13/2008 regarding the rejection of claims 3 and 4 made by the Examiner under 35 USC 112, first paragraph (enablement) have been fully considered and they are found persuasive. This rejection has been overcome by amendment.

4. Applicants arguments filed 08/13/2008 regarding the rejection of claims 1-9 and 20 made by the Examiner under 35 USC 112 first paragraph (written description) have been fully considered and they are found persuasive. This rejection has been overcome by amendment to the specification under 37 CFR 1.57.

5. Applicants arguments filed 08/13/2008 regarding the rejection of claims 1, 2, 5-9 and 20 made by the Examiner under 35 USC 103(a) over Kelly et al. (WO98/08503), supported by Sinha et al. (Photochem. Photobiol. Sci., 2002, 1, 225-236) have been fully considered but they are not found persuasive.

6. Applicants arguments filed 08/13/2008 regarding the rejection of claims 1, 2, 5-9 and 20 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 02/20/2008.

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7. In regards to the 103(a) rejection, Applicant asserts the following:

A) Kelly nor Sinha teach applying topical application of the claimed compounds after UV exposure;

8. With respect to assertion A, it is agreed that neither Kelly or Sinha explicitly teach applying the claimed compounds to the skin after UV exposure. In absence of an explicit teaching, the question becomes: would it have been obvious to one of ordinary skill to think of such? The answer to this question is unequivocally, yes. As noted in the office action, Kelly teaches that the claimed compounds are effective in scavenging and quenching cellular free radicals. Moreover, it is widely known throughout the art, that exposure to UV-radiation produces substantial amounts of free radicals. See Sinha et al.. Sinha states that UV radiation, especially high energy short-wavelength photons absorbed by the chemomorphoc molecules in the skin can lead to the formation of singlet oxygen or free radicals capable of destroying membranes and other components. Exemplified 'other components' includes DNA. Such types of DNA damage include cyclobutane-pyrimidine dimmers and 6-4 photoproducts (see page 226, left column). Taking these two teachings together, it would be obvious even to a below average artisan to if not apply the compounds before exposure to UV radiation, to do so after exposure to UV radiation in order to reduce the likelihood of undesirable results (i.e. cancer, death, etc.). So even though neither of the references directly teaches administering the compounds after UV exposure, it would be obvious and within the purview to an ordinary skilled artisan to arrive at such. Thus, the instantly claimed method is a not a product of innovation, but rather a combination of ordinary skill and common sense. Applicants arguments are not found persuasive.

**New Grounds of Rejection and Objection, Necessitated by Amendment**  
***Claim Objections***

9. Claims 9 and 20 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to the other claims in the alternative only. See MPEP § 608.01(n).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**11. Claims 3 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly et al. (WO98/08503; of record), supported by Sinha et al. (Photochem. Photobiol. Sci., 2002, 1, 225-236; of record).**

12. Kelly and Sinha are relied upon for disclosure described in the rejection of claims 1 and 9 under 35 U.S.C. 103(a).

13. Kelly teaches that various compounds, including those claimed are suitable for treating various types of cancers including breast cancer, uterine cancer, ovarian cancer, testicular cancer, large bowel cancer, endometrial cancer, prostatic cancer and uterine cancer by scavenging the cellular free radicals present in the cancerous cells (see page 7; see instant claim 3). Kelley teaches that their compounds can be present in cosmetic creams as well as in sunscreens (see page 12; see instant claim 24).

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14. Kelly fails to teach the cancer treated as skin cancer.

15. Sinha however teaches that free radical damage which leads to CPD and 6-4 PPs leads to skin cancer (see page 226, right column and page 229, left column).

16. It would have obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Kelly and Sinha with a reasonable expectation for success in arriving at a method of treating skin cancer. With respect to the requirement that the cancer treated by skin cancer, this limitation is obvious. Albeit true that Kelly does not exemplify skin cancer, one of ordinary skill in the art would have reasonable arrived at such a method especially in view of Sinha. As noted above, Sinha teaches that UV exposure upon the skin may lead to skin cancer because of free radical damage. A combination of these two teachings would give one of ordinary skill enough knowledge so as to arrive at a method of reducing the formation of skin cancer by effectively inhibiting free radical damage to the cell. Therefore, a method of treating skin cancer using isoflavone compounds is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

**17. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly et al. (WO98/08503; of record), supported by Sinha et al. (Photochem. Photobiol. Sci., 2002, 1, 225-236; of record) and Fleming et al. (Cancer, 1994, 75:S2, 699-704).**

18. Kelly and Sinha are relied upon for disclosure described in the rejection of claims 1 and 3 under 35 U.S.C. 103(a).

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19. Kelly and Sinha fails to teach the skin cancer as being basal cell carcinoma, squamous cell carcinoma or malignant melanoma.

20. Fleming is a review article directed to the principles of managing basal and squamous cell carcinomas of the skin. Table 1 discloses a skin cancer distribution wherein basal cell and squamous together combine to make up more than 90% of all skin cancers. It is taught that a very common etiology for skin cancer is UV sun exposure (see page 699, right column).

21. It would have obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Kelly and Sinha with a reasonable expectation for success in arriving at a method of treating skin cancer, wherein the cancer is basal cell carcinoma, squamous cell carcinoma or malignant melanoma. With regards to the requirement that the skin cancer be basal cell, squamous or malignant, this requirement is obvious. Fleming teaches that skin cancer distribution is heavily skewed towards basal and squamous cell carcinomas. Thus, one of ordinary skill in the art would have a reasonable expectation that the administering the compounds disclosed by Kelly would reasonable reduce the formation of skin cancer in persons who have been exposed to UV radiation. Therefore, a method of treating skin cancer such as basal cell carcinoma using isoflavone compounds is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

***Maintained Rejections***  
***Claim Rejections - 35 USC § 103***

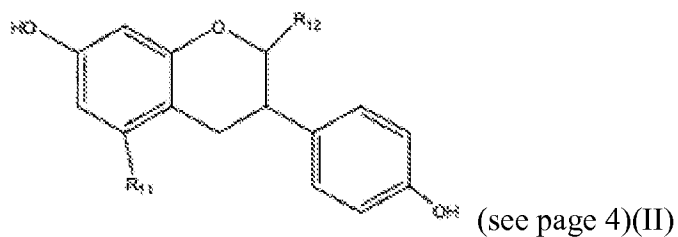
22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**23. Claims 1, 2, 5, 9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly et al. (WO98/08503; of record, see IDS), supported by Sinha et al. (Photochem. Photobiol. Sci., 2002, 1,225-236; of record).**

24. Kelly et al. ('Kelly') is drawn to therapeutic methods and composition involving isoflavones. It is taught that compound 10 having the following molecular structure



wherein when both R11 and R12 are hydrogen, the resulting compound is dehydroequol (see page 27). It is taught that dehydroequol can be used for the treatment of diseases associated with oxidant stress including cancer and sunlight induced skin damage. Such conditions are generally regarded to be associated with oxidant stress, and the above compound treats diseases associated with oxidant stress. It is taught that dehydroequol is highly effective antioxidant (see page 31) which according to the specification and the Example 6, is directly related to the treatment of cancer. Example 6.1 illustrates that dehydroequol is a potent free radical scavenger (see page 32). The compound may be carried in a therapeutic composition such as a cream wherein the active compound is present at a concentration from about 0.5% to 2% (see page 11). It is noted that the cream can be formulated as a cosmetic skin cream to prevent skin aging such as in a sun screen or a shampoo (see page 12).



25. Kelly fails to teach the instantly claimed compound. Moreover, Kelly fails to teach administering the compound after exposure to UV radiation.

26. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teaching of Kelly with a reasonable expectation of success in arriving at a method utilizing a compound capable of enhancing the body defense against UV induced damage. Kelly teaches that the compound dehydroequisol as being capable of treating disease associated with oxidant stress such as cancer and that the compound is highly effective at scavenging free radicals. Although the reference does not specifically teach the elected species, it does teach a structurally analogous compound (compare structures 1 and 2). The major difference between the elected species and the species taught by Kelley is the presence of a methyl group. However the presence of a methyl group in place of a hydrogen does not patentably distinguish the instant species over the prior art species. It is well established that a methyl functionality is structurally analogous to a hydrogen, and absent any secondary results, the elected compound would possess the same functional properties as dehydroequisol. Although dehydroequisol is not taught to possess the ability to promote the expression of metallothionein, it is taught to be capable of scavenging free radicals. Free radical formation is known to induce DNA damage through the formation of CPDs (cyclobutane pyrimidine dimers) (see Sinha et al. (Photochem. Photobiol. Sci., 2002, 1,225-236), so by implementing a compound that scavenges free radicals, it would necessarily reduce the formation of CPDs (i.e. promote repair and reduce potential of DNA damage due to UV-exposure). With respect to the time course of treatment regarding before, during of after UV exposure and the amount of compound, one of ordinary skill in the art would optimize such an application in order to arrive at a method resulting in the

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greatest therapeutic efficacy. Thus, the invention as a whole is prima facie obvious to one ordinarily skilled in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

### ***Conclusion***

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

28. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

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30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/  
Examiner, Art Unit 1611  
October 14, 2008*

*/Sharmila Gollamudi Landau/  
Supervisory Patent Examiner, Art Unit 1611*